

Calendar No. 951

106TH CONGRESS
2D SESSION

S. 1155

[Report No. 106-504]

To amend the Federal Food, Drug, and Cosmetic Act to provide for uniform food safety warning notification requirements, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 27, 1999

Mr. ROBERTS (for himself, Mr. WARNER, Mr. HARKIN, Mr. KERREY, Mr. LUGAR, Mr. McCONNELL, Mr. JOHNSON, Mr. ENZI, Mr. BUNNING, Mr. COCHRAN, Mr. BURNS, Mr. SMITH of Oregon, Mr. SESSIONS, Mr. SANTORUM, Mr. COVERDELL, Mr. CLELAND, Mr. GREGG, Mr. BROWNBACK, Mr. ALLARD, Mr. ABRAHAM, Mr. GRAMS, Mrs. LINCOLN, Mr. ASHCROFT, Mr. HUTCHINSON, Mr. SHELBY, Mr. HELMS, Mr. CRAPO, Mr. GRASSLEY, Mr. ROBB, Mr. BAUCUS, Mr. INHOFE, Mr. FITZGERALD, Mr. GORTON, Mr. REID, and Mr. HATCH) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

OCTOBER 17 (legislative day, SEPTEMBER 22), 2000

Reported by Mr. LUGAR, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italie*]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for uniform food safety warning notification requirements, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “National Uniformity
 5 for Food Act of 1999”.

6 **SEC. 2. NATIONAL UNIFORMITY FOR FOOD.**

7 (a) NATIONAL UNIFORMITY.—Section 403A(a) of the
 8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–
 9 1(a)) is amended—

10 (1) by striking “or” at the end of paragraph
 11 (4);

12 (2) in paragraph (5), by striking the period and
 13 inserting a comma; and

14 (3) by adding at the end the following:

15 “(6) any requirement for the labeling of food
 16 described in section 403(j), or 403(s), that is not
 17 identical to the requirement of such section, or

18 “(7) any requirement for a food described in
 19 section 402(a)(1), 402(a)(2), 402(a)(6), 402(a)(7),
 20 402(e), 402(f), 402(g), 404, 406, 408, 409, 512, or
 21 721(a), that is not identical to the requirement of
 22 such section.”.

23 (b) UNIFORMITY IN FOOD SAFETY WARNING NOTI-
 24 FICATION REQUIREMENTS.—Chapter IV of such Act (21
 25 U.S.C. 341 et seq.) is amended—

1 (1) by redesignating sections 403B and 403C
2 as sections 403C and 403D, respectively; and

3 (2) by inserting after section 403A the fol-
4 lowing new section:

5 **“SEC. 403B. UNIFORMITY IN FOOD SAFETY WARNING NOTI-**
6 **FICATION REQUIREMENTS.**

7 “(a) UNIFORMITY REQUIREMENT.—

8 “(1) IN GENERAL.—Except as provided in sub-
9 sections (b) and (c), no State or political subdivision
10 of a State may, directly or indirectly, establish or
11 continue in effect under any authority any notifica-
12 tion requirement for a food that provides for a warn-
13 ing concerning the safety of the food, or any compo-
14 nent or package of the food, unless such a notifica-
15 tion requirement has been prescribed under the au-
16 thority of this Act and the State or political subdivi-
17 sion notification requirement is identical to the noti-
18 fication requirement prescribed under the authority
19 of this Act.

20 “(2) DEFINITIONS.—For purposes of paragraph
21 (1)—

22 “(A) the term ‘notification requirement’ in-
23 cludes any mandatory disclosure requirement
24 relating to the dissemination of information
25 about a food by a manufacturer or distributor

1 of a food in any manner, such as through a
 2 label, labeling, poster, public notice, advertising,
 3 or any other means of communication, but not
 4 relating to notification, disclosure, or other dis-
 5 semination of information by a State or political
 6 subdivision;

7 “(B) the term ‘warning’, used with respect
 8 to a food, means any statement, vignette, or
 9 other representation that indicates, directly or
 10 by implication, that the food presents or may
 11 present a hazard to health or safety; and

12 (C) a reference to a notification require-
 13 ment that provides for a warning shall not be
 14 construed to refer to any requirement or prohi-
 15 bition relating to food safety that does not in-
 16 volve a notification requirement.

17 “(b) EXEMPTIONS AND NATIONAL STANDARDS.—

18 “(1) EXEMPTIONS.—Any State may petition
 19 the Secretary to provide by regulation, after pro-
 20 viding notice and an opportunity for written and
 21 oral presentation of views during a public comment
 22 period described in paragraph (2), an exemption
 23 from paragraph (6) or (7) of section 403A(a) or
 24 subsection (a), for a requirement of the State or a
 25 political subdivision of the State. The Secretary may

1 provide such an exemption, under such conditions as
2 the Secretary may impose, for such a requirement
3 that—

4 “(A) protects an important public interest
5 that would otherwise be unprotected, in the ab-
6 sence of the exemption;

7 “(B) would not cause any food to be in
8 violation of any applicable requirement or prohi-
9 bition under Federal law; and

10 “(C) would not unduly burden interstate
11 commerce, balancing the importance of the pub-
12 lic interest of the State or political subdivision
13 against the impact on interstate commerce.

14 “(2) NATIONAL STANDARDS.—Any State may
15 petition the Secretary to establish by regulation,
16 after providing notice and an opportunity for written
17 and oral presentation of views during a public com-
18 ment period described in paragraph (3), a national
19 standard respecting any requirement under this Act
20 or the Fair Packaging and Labeling Act (15 U.S.C.
21 1451 et seq.) relating to the regulation of a food.

22 “(3) ACTION ON PETITIONS.—

23 “(A) PUBLICATION.—Not later than 30
24 days after receipt of any petition under para-
25 graph (1) or (2), the Secretary shall publish

1 such petition in the Federal Register for public
2 comment during a period specified by the Sec-
3 retary.

4 “(B) TIME PERIODS FOR ACTION.—Not
5 later than 60 days after the end of the period
6 for public comment, the Secretary shall take ac-
7 tion on the petition. If the Secretary is unable
8 to take action on the petition during the 60-day
9 period, the Secretary shall inform the peti-
10 tioner, in writing, the reasons that taking the
11 action is not possible, the date by which the ac-
12 tion will be taken, and the action that will be
13 taken or is likely to be taken. In every case, the
14 Secretary shall take action on the petition not
15 later than 120 days after the end of the period
16 for public comment.

17 “(4) JUDICIAL REVIEW.—The failure of the
18 Secretary to comply with any requirement of this
19 subsection shall constitute final agency action for
20 purposes of judicial review. If the court conducting
21 the review determines that the Secretary has failed
22 to comply with the requirement, the court shall
23 order the Secretary to comply within a period deter-
24 mined to be appropriate by the court.

25 “(c) IMMINENT HAZARD AUTHORITY.—

1 “(1) IN GENERAL.—A State may establish a re-
 2 quirement that would otherwise violate paragraph
 3 (6) or (7) of section 403A(a) or subsection (a), if—

4 “(A) the requirement is needed to address
 5 an imminent hazard to health that is likely to
 6 result in serious adverse health consequences or
 7 death;

8 “(B) the State has informed the Secretary
 9 about the matter involved and the Secretary
 10 has not initiated enforcement or other regu-
 11 latory action with respect to the matter;

12 “(C) a petition is submitted by the State
 13 under subsection (b) for an exemption or na-
 14 tional standard relating to the requirement not
 15 later than the date that the State establishes
 16 the requirement under this subsection; and

17 “(D) the State institutes enforcement ac-
 18 tion with respect to the matter in compliance
 19 with State law following submission of such pe-
 20 tition.

21 “(2) ACTION ON PETITION.—

22 “(A) IN GENERAL.—The Secretary shall
 23 take action on any petition submitted under
 24 paragraph (1)(C) not later than 7 days after
 25 the petition is received, notwithstanding sub-

1 section (b)(3)(B) and the public comment re-
2 quirements of subsection (b):

3 ~~“(B) JUDICIAL REVIEW.—~~The failure of
4 the Secretary to comply with the requirement
5 described in subparagraph (A) shall constitute
6 final agency action for purposes of judicial re-
7 view. If the court conducting the review deter-
8 mines that the Secretary has failed to comply
9 with the requirement, the court shall order the
10 Secretary to comply within a period determined
11 to be appropriate by the court.

12 ~~“(3) DURATION.—~~If a State establishes a re-
13 quirement in accordance with paragraph (1), the re-
14 quirement may remain in effect until the Secretary
15 acts on a petition submitted under paragraph
16 (1)(C).

17 ~~“(d) NO EFFECT ON PRODUCT LIABILITY LAW.—~~
18 Nothing in this section shall be construed to modify or
19 otherwise affect the product liability law of any State.

20 ~~“(e) NO EFFECT ON IDENTICAL LAW.—~~Nothing in
21 this section or section 403A relating to a food shall be
22 construed to prevent a State or political subdivision of a
23 State from establishing, enforcing, or continuing in effect
24 a requirement that is identical to a requirement of this
25 Act, whether or not the Secretary has promulgated a regu-

1 lation or issued a policy statement relating to the require-
 2 ment.

3 “(f) NO EFFECT ON CERTAIN STATE LAW.—Nothing
 4 in this section or section 403A relating to a food shall
 5 be construed to prevent a State or political subdivision of
 6 a State from establishing, enforcing, or continuing in ef-
 7 fect a requirement relating to—

8 “(1) freshness dating, open date labeling, grade
 9 labeling, a State inspection stamp, religious dietary
 10 labeling, organic or natural designation, returnable
 11 bottle labeling, unit pricing, or a statement of geo-
 12 graphic origin; or

13 “(2) a consumer advisory relating to food sani-
 14 tation that is imposed on a food service establish-
 15 ment, or that is recommended by the Secretary,
 16 under part 3–6 of the Food Code issued by the Food
 17 and Drug Administration and referred to in the no-
 18 tice published at 64 Fed. Reg. 8576 (1999) (or any
 19 corresponding similar provision of such a Code).”

20 (e) CONFORMING AMENDMENT.—Section 403A(b) of
 21 such Act (21 U.S.C. 343–1(b)) is amended by adding at
 22 the end the following:

23 “The requirements of paragraphs (3) and (4) of section
 24 403B(b) shall apply to any such petition, in the same

1 manner and to the same extent as the requirements apply
 2 to a petition described in section 403B(b).”.

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “National Uniformity*
 5 *for Food Act of 2000”.*

6 **SEC. 2. NATIONAL UNIFORMITY FOR FOOD.**

7 (a) *NATIONAL UNIFORMITY.*—Section 403A(a) of the
 8 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–*
 9 *1(a)) is amended—*

10 (1) *by striking “or” at the end of paragraph (4);*

11 (2) *in paragraph (5), by striking the period and*
 12 *inserting a comma; and*

13 (3) *by adding at the end the following:*

14 “(6) *any requirement for the labeling of food de-*
 15 *scribed in section 403(j), or 403(s), that is not iden-*
 16 *tical to the requirement of such section, or*

17 “(7) *any requirement for a food described in sec-*
 18 *tion 402(a)(1), 402(a)(2), 402(a)(6), 402(a)(7),*
 19 *402(c), 402(f), 402(g), 404, 406, 408, 409, 512, or*
 20 *721(a), that is not identical to the requirement of*
 21 *such section.”.*

22 (b) *UNIFORMITY IN FOOD SAFETY WARNING NOTIFICA-*
 23 *TION REQUIREMENTS.*—Chapter IV of such Act (21 U.S.C.
 24 *341 et seq.) is amended—*

1 (1) *by redesignating sections 403B and 403C as*
 2 *sections 403C and 403D, respectively; and*

3 (2) *by inserting after section 403A the following*
 4 *new section:*

5 **“SEC. 403B. UNIFORMITY IN FOOD SAFETY WARNING NOTI-**
 6 **FICATION REQUIREMENTS.**

7 “(a) *UNIFORMITY REQUIREMENT.—*

8 “(1) *IN GENERAL.—Except as provided in sub-*
 9 *sections (c) and (d), no State or political subdivision*
 10 *of a State may, directly or indirectly, establish or*
 11 *continue in effect under any authority any notifica-*
 12 *tion requirement for a food that provides for a warn-*
 13 *ing concerning the safety of the food, or any compo-*
 14 *nent or package of the food, unless such a notification*
 15 *requirement has been prescribed under the authority*
 16 *of this Act and the State or political subdivision noti-*
 17 *fication requirement is identical to the notification*
 18 *requirement prescribed under the authority of this*
 19 *Act.*

20 “(2) *DEFINITIONS.—For purposes of paragraph*
 21 (1)—

22 “(A) *the term ‘notification requirement’ in-*
 23 *cludes any mandatory disclosure requirement re-*
 24 *lating to the dissemination of information about*
 25 *a food by a manufacturer or distributor of a food*

1 *in any manner, such as through a label, labeling,*
 2 *poster, public notice, advertising, or any other*
 3 *means of communication, except as provided in*
 4 *paragraph (3);*

5 *“(B) the term ‘warning’, used with respect*
 6 *to a food, means any statement, vignette, or*
 7 *other representation that indicates, directly or by*
 8 *implication, that the food presents or may*
 9 *present a hazard to health or safety; and*

10 *“(C) a reference to a notification require-*
 11 *ment that provides for a warning shall not be*
 12 *construed to refer to any requirement or prohibi-*
 13 *tion relating to food safety that does not involve*
 14 *a notification requirement.*

15 *“(3) CONSTRUCTION.—Nothing in this section*
 16 *shall be construed to prohibit a State from conducting*
 17 *the State’s notification, disclosure, or other dissemi-*
 18 *nation of information, or to prohibit any action*
 19 *taken relating to a mandatory recall or court injunc-*
 20 *tion involving food adulteration under a State statu-*
 21 *tory requirement identical to a food adulteration re-*
 22 *quirement under this Act.*

23 *“(b) REVIEW OF EXISTING STATE REQUIREMENTS.—*

24 *“(1) EXISTING STATE REQUIREMENTS; DEFER-*
 25 *RAL.—Any requirement that—*

1 “(A)(i) is a State notification requirement
 2 for a food that provides for a warning described
 3 in subsection (a) that does not meet the uni-
 4 formity requirement specified in subsection (a);
 5 or

6 “(ii) is a State food safety requirement de-
 7 scribed in paragraph (6) or (7) of section 403A
 8 that does not meet the uniformity requirement
 9 specified in that paragraph; and

10 “(B) is in effect on the date of enactment of
 11 the National Uniformity for Food Act of 2000,
 12 shall remain in effect for 180 days after that date of
 13 enactment.

14 “(2) STATE PETITIONS.—With respect to a State
 15 notification or food safety requirement that is de-
 16 scribed in paragraph (1), the State may petition the
 17 Secretary for an exemption or a national standard
 18 under subsection (c). If a State submits such a peti-
 19 tion within 180 days after the date of enactment of
 20 the National Uniformity for Food Act of 2000, the no-
 21 tification or food safety requirement shall remain in
 22 effect until the Secretary takes all administrative ac-
 23 tion on the petition pursuant to paragraph (3), and
 24 the time periods and provisions specified in para-
 25 graph (3) shall apply in lieu of the time periods and

1 *provisions specified in subsection (c)(3) (but not the*
 2 *time periods and provisions specified in subsection*
 3 *(d)(2)).*

4 “(3) *ACTION ON PETITIONS.*—

5 “(A) *PUBLICATION.*—*Not later than 270*
 6 *days after the date of enactment of the National*
 7 *Uniformity for Food Act of 2000, the Secretary*
 8 *shall publish a notice in the Federal Register*
 9 *concerning any petition submitted under para-*
 10 *graph (2) and shall provide 180 days for public*
 11 *comment on the petition.*

12 “(B) *TIME PERIODS.*—*Not later than 360*
 13 *days after the end of the period for public com-*
 14 *ment, the Secretary shall take final agency ac-*
 15 *tion on the petition.*

16 “(C) *JUDICIAL REVIEW.*—*The failure of the*
 17 *Secretary to comply with any requirement of*
 18 *this paragraph shall constitute final agency ac-*
 19 *tion for purposes of judicial review. If the court*
 20 *conducting the review determines that the Sec-*
 21 *retary has failed to comply with the requirement,*
 22 *the court shall order the Secretary to comply*
 23 *within a period determined to be appropriate by*
 24 *the court.*

25 “(c) *EXEMPTIONS AND NATIONAL STANDARDS.*—

1 “(1) *EXEMPTIONS.*—Any State may petition the
 2 Secretary to provide by regulation an exemption from
 3 paragraph (6) or (7) of section 403A(a) or subsection
 4 (a), for a requirement of the State or a political sub-
 5 division of the State. The Secretary may provide such
 6 an exemption, under such conditions as the Secretary
 7 may impose, for such a requirement that—

8 “(A) protects an important public interest
 9 that would otherwise be unprotected, in the ab-
 10 sence of the exemption;

11 “(B) would not cause any food to be in vio-
 12 lation of any applicable requirement or prohibi-
 13 tion under Federal law; and

14 “(C) would not unduly burden interstate
 15 commerce, balancing the importance of the pub-
 16 lic interest of the State or political subdivision
 17 against the impact on interstate commerce.

18 “(2) *NATIONAL STANDARDS.*—Any State may pe-
 19 tition the Secretary to establish by regulation a na-
 20 tional standard respecting any requirement under
 21 this Act or the Fair Packaging and Labeling Act (15
 22 U.S.C. 1451 et seq.) relating to the regulation of a
 23 food.

24 “(3) *ACTION ON PETITIONS.*—

1 “(A) *PUBLICATION.*—Not later than 30
2 days after receipt of any petition under para-
3 graph (1) or (2), the Secretary shall publish such
4 petition in the Federal Register for public com-
5 ment during a period specified by the Secretary.

6 “(B) *TIME PERIODS FOR ACTION.*—Not
7 later than 60 days after the end of the period for
8 public comment, the Secretary shall take final
9 agency action on the petition. If the Secretary is
10 unable to take final agency action on the peti-
11 tion during the 60-day period, the Secretary
12 shall inform the petitioner, in writing, the rea-
13 sons that taking the final agency action is not
14 possible, the date by which the final agency ac-
15 tion will be taken, and the final agency action
16 that will be taken or is likely to be taken. In
17 every case, the Secretary shall take final agency
18 action on the petition not later than 120 days
19 after the end of the period for public comment.

20 “(4) *JUDICIAL REVIEW.*—The failure of the Sec-
21 retary to comply with any requirement of this sub-
22 section shall constitute final agency action for pur-
23 poses of judicial review. If the court conducting the
24 review determines that the Secretary has failed to
25 comply with the requirement, the court shall order the

1 *Secretary to comply within a period determined to be*
 2 *appropriate by the court.*

3 “(d) *IMMINENT HAZARD AUTHORITY.*—

4 “(1) *IN GENERAL.*—*A State may establish a re-*
 5 *quirement that would otherwise violate paragraph (6)*
 6 *or (7) of section 403A(a) or subsection (a), if—*

7 “(A) *the requirement is needed to address*
 8 *an imminent hazard to health that is likely to*
 9 *result in serious adverse health consequences or*
 10 *death;*

11 “(B) *the State has notified the Secretary*
 12 *about the matter involved and the Secretary has*
 13 *not initiated enforcement action with respect to*
 14 *the matter;*

15 “(C) *a petition is submitted by the State*
 16 *under subsection (c) for an exemption or na-*
 17 *tional standard relating to the requirement not*
 18 *later than 30 days after the date that the State*
 19 *establishes the requirement under this subsection;*
 20 *and*

21 “(D) *the State institutes enforcement action*
 22 *with respect to the matter in compliance with*
 23 *State law within 30 days after the date that the*
 24 *State establishes the requirement under this sub-*
 25 *section.*

1 “(2) *ACTION ON PETITION.*—

2 “(A) *IN GENERAL.*—*The Secretary shall*
 3 *take final agency action on any petition sub-*
 4 *mitted under paragraph (1)(C) not later than 7*
 5 *days after the petition is received, and the provi-*
 6 *sions of subsection (c) shall not apply to the peti-*
 7 *tion.*

8 “(B) *JUDICIAL REVIEW.*—*The failure of the*
 9 *Secretary to comply with the requirement de-*
 10 *scribed in subparagraph (A) shall constitute*
 11 *final agency action for purposes of judicial re-*
 12 *view. If the court conducting the review deter-*
 13 *mines that the Secretary has failed to comply*
 14 *with the requirement, the court shall order the*
 15 *Secretary to comply within a period determined*
 16 *to be appropriate by the court.*

17 “(3) *DURATION.*—*If a State establishes a re-*
 18 *quirement in accordance with paragraph (1), the re-*
 19 *quirement may remain in effect until the Secretary*
 20 *takes final agency action on a petition submitted*
 21 *under paragraph (1)(C).*

22 “(e) *NO EFFECT ON PRODUCT LIABILITY LAW.*—*Noth-*
 23 *ing in this section shall be construed to modify or otherwise*
 24 *affect the product liability law of any State.*

1 “(f) *NO EFFECT ON IDENTICAL LAW.*—*Nothing in this*
 2 *section or section 403A relating to a food shall be construed*
 3 *to prevent a State or political subdivision of a State from*
 4 *establishing, enforcing, or continuing in effect a require-*
 5 *ment that is identical to a requirement of this Act, whether*
 6 *or not the Secretary has promulgated a regulation or issued*
 7 *a policy statement relating to the requirement.*

8 “(g) *NO EFFECT ON CERTAIN STATE LAW.*—*Nothing*
 9 *in this section or section 403A relating to a food shall be*
 10 *construed to prevent a State or political subdivision of a*
 11 *State from establishing, enforcing, or continuing in effect*
 12 *a requirement relating to—*

13 “(1) *freshness dating, open date labeling, grade*
 14 *labeling, a State inspection stamp, religious dietary*
 15 *labeling, organic or natural designation, returnable*
 16 *bottle labeling, unit pricing, or a statement of geo-*
 17 *graphic origin; or*

18 “(2) *a consumer advisory relating to food sanita-*
 19 *tion that is imposed on a food establishment, or that*
 20 *is recommended by the Secretary, under part 3–6 of*
 21 *the Food Code issued by the Food and Drug Adminis-*
 22 *tration and referred to in the notice published at 64*
 23 *Fed. Reg. 8576 (1999) (or any corresponding similar*
 24 *provision of such a Code).*

1 “(h) *DEFINITION.*—In section 403A and this section,
 2 the term ‘requirement’, used with respect to a Federal action
 3 or prohibition, means a mandatory action or prohibition
 4 established under this Act or the Fair Packaging and Label-
 5 ing Act (15 U.S.C. 1451 et seq.), as appropriate, or by a
 6 regulation issued under or by a court order relating to, this
 7 Act or the Fair Packaging and Labeling Act, as appro-
 8 priate.”.

9 (c) *CONFORMING AMENDMENT.*—Section 403A(b) of
 10 such Act (21 U.S.C. 343–1(b)) is amended by adding at
 11 the end the following:
 12 “The requirements of paragraphs (3) and (4) of section
 13 403B(c) shall apply to any such petition, in the same man-
 14 ner and to the same extent as the requirements apply to
 15 a petition described in section 403B(c).”.

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A BILL

To amend the Federal Food, Drug, and Cosmetic
Act to provide for uniform food safety warning
notification requirements, and for other purposes.

OCTOBER 17 (legislative day, SEPTEMBER 22), 2000

Reported with an amendment